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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,617	02/21/2002	Steffen Panzner	101215-81	9573
27387	7590	11/03/2004	EXAMINER	
NORRIS, MCLAUGHLIN & MARCUS, P.A. 875 THIRD AVE 18TH FLOOR NEW YORK, NY 10022			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/081,617

Applicant(s)

PANZNER ET AL.

Examiner

Gollamudi S Kishore, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-13 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Applicant's election without traverse of Group I, in the reply filed on 8-13-04 is acknowledged.

The claims included in the prosecution are 1-3, 5-11 and 20.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-3, 5-11 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'one positive charge carrier and at least one negative charge carrier, which is different from the positive charge carrier –' in claim 1. Aren't positive charge carriers and negative charge carriers inherently different from each other because they do not have the same charge and therefore different compounds?

According to claim 1, the liposome has an isoelectric point between 4 and 8 and the liposomes contain either positively charged or negatively charged compounds. If the isoelectric point of the amphoteric charge carrier itself is between 4-8, won't it affect the isoelectric point of 'whole liposome'?

It is unclear whether the neutral lipid recited in claim 7 is present in addition. If so, the examiner suggests, "further comprising".

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It is unclear whether the sizes recited after the terms, 'preferably' and 'particularly' in claim 8 are indeed the limitations.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Millet-Gemin (5,290,563) or Dees (4,599,227) or Delrieu (5,962,015).

Instant claims are drawn to amphoteric liposomes requiring a combination of one positive charge carrier and either a negative charge carrier OR an amphoteric charge carrier. According to instant claim 5, the liposomes contain an amphoteric charge carrier in combination with either positively charged or negatively charged carrier.

Millet-Genin discloses liposomes containing phosphatidylcholine (amphoteric agent) and stearylamine (positively charge carrier) encapsulating allergens. The liposomes are small unilamellar which implies that they have the diameter within the claimed range (abstract, col. 3, lines 1-54 and claims).

Similarly, Dees discloses liposomes containing phosphatidylcholine (amphoteric agent) and stearylamine (positively charge carrier) encapsulating proteins. The liposomes have a diameter of 75 to 200 nm (abstract, col. 7, line 54, Examples and claims).

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Delrieu discloses liposomes containing phosphatidylcholine (amphoteric agent) and either stearylamine or quaternary ammonium compounds (positively charge carrier) encapsulating proteins. The liposomes are small unilamellar, which implies that they have the diameter within the claimed range (abstract, Examples and claims).

The references are silent with respect to the isoelectric point of the liposome itself. However, since it has the same combination of the lipids making up the liposomes and therefore, in the absence of showing otherwise, it is deemed that the isoelectric point is an inherent property of this liposome.

5. Claims 1-3, 5-11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kripke (5,302,389) or Yarosh (5,296,231).


The references of Kripke, and Yarosh each discloses liposomes having phosphatidylcholine (neutral lipid), phosphatidylethanolamine (positive charge carrier lipid), oleic acid (negative charge carrier) and cholesterol hemisuccinate (CHEMS) (Example 1 on col. 5 of Kripke; abstract, Examples and claims of Yarosh). The references are silent with respect to the isoelectric point. However, since it has the same combination of the lipids making up the liposomes and therefore, in the absence of showing otherwise, it is deemed that the isoelectric point is an inherent property of this liposome. The references are also silent with regard to the sizes of liposomes. However, since the references teach sonication (see Example 3 in Yarosh for example), and in view of the broad range of diameters claimed, it is deemed that instant sizes are deemed to be implicit in the references.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK